

## **AMENDMENTS TO THE DRAWINGS**

The attached "Replacement Sheets" of drawings includes changes to Figures 4 - 19 and 21. The attached "Replacement Sheets," which includes Figures 1-22, replaces the original sheets including Figures 1-22.

Attachment: Replacement Sheets

## **REMARKS**

Claims 1-16, 18-26, and 28-51 are now pending in the application. Claims 17 and 27 are canceled and Claims 48-51 are added by this amendment. Claims 1, 16, 21, and 37 are amended by this amendment. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

## **DRAWINGS**

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the reference arrows in Figures 4-19 and 21 are lost in the background shade which prevents each reference number from identifying its element.

Line drawings have been provided for portions of Figs. 1, 4-19, and 21 where shaded figures were previously used. Replacement Sheets include all of the figures 1-22 for completeness. No new subject matter has been added by this amendment.

## **INFORMATION DISCLOSURE STATEMENT**

Applicants and Applicants' representative submit that they have met their duty as required by 37 C.F.R. § 1.56, which states:

Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.

Applicants and Applicants' representative have attempted to follow the suggestions of the U.S. Pat. and Trademark Office, as set forth in the M.P.E.P. 2001.05, which states:

The Office believes that most applicants will wish to submit the information, however, even though they may not be required to do so, to strengthen the patent and avoid the risks of an incorrect judgment on their part on materiality or that it may be held that there was an intent to deceive the Office.

Applicants and Applicants' representative believe that a cautious and inclusive interpretation of the duty is further required by M.P.E.P. 2001.04, which states:

The Office does not anticipate any significant change in the quantity of information cited to the Office. Presumably, applicants will continue to submit information for consideration by the Office in applications rather than making and relying on their own determinations of materiality. An incentive remains to submit the information to the Office because it will result in a strengthened patent and will avoid later questions of materiality and intent to deceive.

and M.P.E.P. 2004, which states:

When in doubt, it is desirable and safest to submit information. Even though the attorney, agent, or applicant doesn't consider it necessarily material, someone else may see it differently and embarrassing questions can be avoided. The court in *U.S. Industries v. Norton Co.*, 210 USPQ 94, 107 (N.D. N.Y. 1980) stated "In short, the question of relevancy in close cases, should be left to the examiner and not the applicant." See also *LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 22 USPQ2d 1025 (Fed. Cir. 1992).

Accordingly, Applicants and Applicants' representative believe that their duty has been met under §1.56 and believe that no further statements need be provided to the

Office under M.P.E.P. 2004 regarding the information provided in the Information Disclosure Statements.

Applicants have also submitted all information for consideration by the Examiner in a Form 1449 which lists the references and includes a column for the Examiner's initials. The M.P.E.P. 609.05(b) states:

The information contained in information disclosure statements which comply with both the content requirements of 37 CFR 1.98 and the requirements, based on the time of filing the statement, of 37 CFR 1.97 will be considered by the examiner. Consideration by the examiner of the information submitted in an IDS means that the examiner will consider the documents in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. The initials of the examiner placed adjacent to the citations on the \*\* PTO/SB/08A and 08B or its equivalent mean that the information has been considered by the examiner to the extent noted above.

Examiners must consider all citations submitted in conformance with the rules, and their initials when placed adjacent to the considered citations on the list or in the boxes provided on a form \*\* PTO/SB/08A and 08B provides a clear record of which citations have been considered by the Office.

Because all of the information submitted for consideration by the Examiner was submitted as required by the rules, Applicants submit that the Examiner's initials next to all of the citations indicates that all of the references cited by Applicants have been considered in the same manner as other documents in Office search files.

#### **REJECTION UNDER 35 U.S.C. § 102 AND 103**

Claims 1 stand rejected under 35 U.S.C. § 102(b) as being anticipated by G. Penney et al. "Validation of a two- or three-dimensional registration algorithm for aligning preoperative CT images and intraoperative fluoroscopy images"

(“Penney”). Claims 2-15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Penney in view of the Series 9600 Mobile Digital Imaging System (Series 9600). Claims 12-13 and 16-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Penney in view of the Series 9600 as applied to Claims 2-11 above, and further in view of Penney et al. “A Comparison of Similarity Measures for Use in 2-D-3-D Medical Image Registration” (“Penney II”). Claims 24-42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Penney, Series 9600 and Penney II as applied to Claims 16-23 above, and further in view of B. Schueler et al. “Correction of image intensifier distortion for three-dimensional x-ray angiography.” These rejections are respectfully traversed.

The reference to Penney et al. entitled “Validation of a two- or three-dimensional registration algorithm for aligning preoperative CT images and intraoperative fluoroscopy images” (herein “Penney”) is directed to a system that allows for registration of two-dimensional image data and three-dimensional image data. While Penney is directed to determining consistency between multiple registrations, Penney discloses that the measure of consistency differs from precision or accuracy measurements. See, Penney, pg. 1028, Section C. Therefore, as discussed further herein, Penney fails to disclose various portions of the process presently claimed as Penney is directed to comparing various registration algorithms.

The reference to Penney et al. entitled “A Comparison of Similarity Measures for Use in 2-D-3-D Medical Image Registration” (Herein “Penney II”) is also directed to comparing various similarity measures for 2-D to 3-D image registration. See, Penney II

Abstract. Penney II discloses various similarity measures and assessing the accuracy of each compared to a gold standard, which is a registration based on fiducials.

Schueler et al. is directed to an algorithm to correct pin cushion distortion and s-distortion spatial distortion from an image intensifier for 3-dimensional x-ray angiography. Schueler et al. discusses a system to correct only the spatial distortion in an image.

The subject application, as filed, indicates that “an example of a fluoroscopic C-arm x-ray imaging device 16 is the “Series 9600 Mobile Digital Imaging System,” from OEC Medical Systems, Inc., of Salt Lake City, Utah.” See, the subject application paragraph 26.

Regarding independent Claim 1, which has been amended to include determining how the patient was positioned or oriented relative to an imaging device and “determining an estimate of the patient’s orientation with respect to a dynamic reference frame based at least in part on (a).” Applicants respectfully submit that the cited references do not anticipate or fairly render obvious the first patient orientation information, the second patient orientation information, or determining an estimate as recited in independent Claim 1. As discussed above, Penney and Penney II are directed to comparing differing similarity measures and neither disclose, nor fairly render obvious using or determining patient orientation information or determining an estimate of the patient’s orientation relative to a dynamic reference frame.

Further, the claims that depend directly or indirectly from independent Claim 1 include patentable subject matter. For example, dependent Claim 7 recites “further comprising refining the registration of the two-dimensional image data with the three-

dimensional image data.” While Penney and Penney II are directed to comparing similarity measures, Penney and Penney II fail to disclose or fairly render obvious refining, as recited in dependent Claim 7. Moreover, Applicants respectfully submit that Penney does not disclose or fairly render obvious refining a registration with three-dimensional image data. Penney discloses that an algorithm produces a DRR which is compared to a fluoroscopy image. Therefore, Penney actually teaches away from using three-dimensional image data, as recited in dependent Claim 7. Accordingly, dependent Claim 7 includes subject matter that is in condition for allowance.

In addition, dependent Claim 8 recites “wherein the refined registration employs at least two similarity/cost measures.” Again, Penney discloses various costs or similarity measures and compares them. Penney, however, does not disclose refining a registration that employs at least two similarity/cost measures. In fact Penney, in comparing the multiple similarity measures, actually teaches away from using at least two to refine a registration. That is, Penney reviews similarity measures and determines or attempts to measure which works better than another, rather than employing at least two to refine a registration of two image data sets during a registration process of the image data sets, particularly during a navigated procedure.

Finally, Applicants note that Penney and Penney II are directed to registering a CT volume to a fluoroscopy image. A DRR, as noted in both Penney and Penney II, is created from a CT volume and a fluoroscope creates a different type of image. Thus, Applicants respectfully disagree with the assertion of the Office that “the use of the 9600 to acquire the digital images for the benefit of generating a DRR” is improper as the

Series 9600, as noted in the application as filed, is a C-arm fluoroscope device and not a CT scanner. See, Office Action mailed July 18, 2007, p. 5.

Therefore, independent Claim 1, and the claims that depend directly or indirectly therefrom, is in condition for allowance. Applicants respectfully submit that Penney, Penney II, and Schueler et al., either alone or in combination, do not anticipate or fairly render obvious each of these claims.

Independent Claim 16 has been amended to recite, “registering the two-dimensional image data with the three-dimensional image data using both a first similarity/cost measure and a second similarity/cost measure; and displaying a single registered image based upon the registration of the two-dimensional image data with the three-dimensional image data on a display.” As discussed above, none of the cited references to Penney, Penney II or Schueler et al. disclose or fairly render obvious using both a first and a second similarity/cost measure. Further, none of the references, either alone or in combination, disclose or fairly render obvious displaying a single registered image based upon the registration. Therefore, independent Claim 16 is in condition for allowance in light of the cited art.

Further, claims that depend directly or indirectly from independent Claim 16 also include patentable subject matter. For example, dependent Claim 21 recites “verifying a registration accuracy including displaying a graph of the registration process illustrating the convergence of the process to an answer.” Applicants respectfully submit that the cited references do not disclose a verification process as recited in dependent Claim 21.

Further, dependent Claim 45 recites “verifying registration accuracy including: selecting a point in the acquired three-dimensional image data and representing the

selected point on a display relative to the acquired two-dimensional image data." Again, Applicants respectfully submit that verifying registration accuracy as recited in dependent Claim 45 is not anticipated or fairly rendered obvious by the cited references.

In addition, dependent Claim 19 recites "normalized mutual information and . . . pattern intensity." The use of both normalized mutual information and pattern intensity, as recited in dependent Claim 19, and a single registration process is not anticipated or rendered obvious by the cited references. Rather, as discussed above, using any two similarity or cost measures in a single process is actually taught away from, based on the cited references.

Therefore, independent Claim 16 and the claims that depend therefrom are in condition for allowance.

Regarding independent Claim 28, Applicants respectfully disagree with the Office's assertion that Schueler et al. discloses "performing intensity adjustment of the two-dimensional image to reduce the effect of an interfering object." Rather, Schueler et al. clearly discloses that "an algorithm has been developed to correct for spatial distortion." See, Schueler et al., abstract. Further, Schueler et al. states that the spatial distortion being corrected includes pincushion and S-distortion. See, Schueler et al. p. 272. The technique used is a piecewise spatial warping technique rather than a global correction function. See, Schueler et al. abstract and p. 273. In fact, Schueler et al. only appears to discuss brightness in regards to the fact that an image intensifier may not produce uniform brightness and that this is corrected with a masking technique. See, Schueler et al. p. 274. Accordingly, Applicants submit that Schueler et al., either

alone or in combination with the other cited art, fails to disclose at least the recitation noted above for independent Claim 28.

Finally, regarding independent Claim 37, Applicants respectfully submits that each of the elements recited in independent Claim 37 are not disclosed or fairly rendered obvious by the cited references. For example, independent Claim 37 recites “identifying the center of the body of interest in the first and second two-dimensional images.” While Penney does disclose identifying a region of interest, Penney discloses only that a single point, for a point picking exercise, includes the tip of a spinous process. See, Penney, pg. 1029. Therefore, Applicants respectfully submit that Penney does not disclose or render obvious each of the elements of independent Claim 37. Further, independent Claim 37 recites “registering the first and second two-dimensional images with the three-dimensional image data using at least both a first similarity/cost measure and a second similarity/cost measure.” As discussed above, Applicants respectfully submit that the cited references actually teach away from using both a first and second similarity/cost measure. Therefore, independent Claim 37 is neither anticipated nor rendered obvious by the cited references.

Further, claims that depend directly or indirectly from independent Claim 37 include a patentable subject matter. For example, dependent Claim 39 recites “comprising performing intensity adjustment on the two-dimensional lateral image.” As discussed above, Schueler et al. is directed to spatial distortion correction and fails to disclose performing an intensity adjustment as recited in dependent Claim 39. The other cited references fail to overcome the lack of disclosure of Schueler et al. Therefore, dependent Claim 39 includes patentable subject matter. Applicants also

respectfully submit that the process recited in dependent Claims 40-42, relating to the first second similarity/cost measures, can not be anticipated or rendered obvious by the cited references, as the cited references fail to disclose or fairly render obvious using the first and second similarity/cost measure.

Further, new dependent Claims 46 and 47 are directed to identifying the center of a vertebral body. For example, dependent Claim 47 recites “using the atlas map to provide at least an initial estimate for the center of the vertebral body.” Applicants respectfully submit that the cited references, either alone or in combination, fail to disclose or fairly render obvious an atlas map or using the atlas map as recited in dependent Claim 47.

Therefore, independent Claim 37, and each of the claims that depend directly or indirectly therefrom, are in condition for allowance.

Applicants respectfully submit that each of the presently pending claims are in condition for allowance. If any of the presently pending claims remain rejected, Applicants respectfully request that the specific portions of the cited references be identified in relation to each of the elements of the pending claims so that Applicants can properly respond thereto.

### **New Claims**

New Claims 48-51 are within the scope of the original claims and that they are fully supported by the application as filed. moreover, Applicants submit that each of the new claims are in condition for allowance as they are not anticipated or rendered obvious by the cited art.

For example, independent Claim 48 recites, "displaying the first and second two-dimensional images; identifying a center of the vertebral body of interest with the displayed first and second two-dimensional images." Identifying a center with displayed images is not disclosed or rendered obvious by the cited art. In addition, "aligning the first and second two-dimensional image with the respective digitally reconstructed radiographs" is also not disclosed or fairly rendered obvious by the cited art. Accordingly, "after aligning first and second two-dimensional image with the respective digitally reconstructed radiographs, registering the first and second two-dimensional images with the three-dimensional image data using at least both the first similarity/cost measure and the second similarity/cost measure, including optimizing both the first similarity/cost measure and the second similarity/cost measure" is also not anticipated or fairly rendered obvious by the cited art.

Thus, new Claims 48-51 are in condition for allowance in light of the cited art.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

Dated: Dec. 18, 2007

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